

## **DETAILED ACTION**

Claims 1-12 are pending. This is the first action on the merits of the claims.

Preliminary amendment filed on October 7, 2004 to amend the specification and amend the claims to eliminate multiple dependencies has been received and acknowledged.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Stankov (U.S. Patent No. 5,880,101, as disclosed by applicant). Stankov teaches a method for treating a patient with breast cancer with nystatin, which is claimed in instant claim 1 (column 43, example 20 and column 1, line 31).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stankov (U.S. Patent No. 5,880,101, as disclosed by applicant), Rao et al. (Proceeding of the National Academy of Sciences, Vol. 96, ppp.7797-7802, 1999), Nishimura et al. (Japanese Journal of Cancer Research, Vol. 60, Issue 11, pp. 1224-30, abstract, 1999), and Daubert et al. (U.S. Patent Publication No. 2001/0000793).

Stankov teaches a method for treating a patient with breast cancer with nystatin which is claimed in instant claim 1 (column 43, example 20 and column 1, line 31).

Stankov does not disclose the use of the nystatin in combination of a cholesterol lowering agent.

Rao et al. teaches the use of lovastatin functions as a chemopreventive agent by inhibition of the proteasome, resulting in increased stabilization of p21 and p27, which have tumor suppressive abilities (p. 7802, lines 1-5).

Nishimura et al. discloses the use of probucol for treating cancer (Abstract, last line).

Daubert et al. discloses a vial for pharmaceuticals (paragraph [0074])

It would have prima facie obvious to use nystatin to treat a patient with breast cancer as taught by Stankov et al. in combination with the lovastatin as taught by Rao et al. and the probucol as taught by Nishimura et al. It is known in the cancer art to use combination therapy. It is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. It would prima facie obvious to use the vial for pharmaceuticals as taught by Daubert et al. with the teachings of Stankov et al. and Rao et al. Printed material has no patentable weight.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 730am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867 or Cecilia Tsang on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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